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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,443	05/07/2007	Shoji Fukumoto	20039.0006USWO	7172

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EXAMINER	
SOLOLA, TAOFIQ A	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
05/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,443	FUKUMOTO ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7,16 and 18-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-27* is/are rejected.

7)☒ Claim(s) *6,7,16,18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-30 are pending in this application.

Claims 1-5, 8-15, 17, 28, are deleted.

Restriction

The restriction of group III, claims 19-27, is now withdrawn and the groups are rejoined with the elected invention of group I. Under the Rule of Rejoinder such is deemed an amendment.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26-27, are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Under US patent practice, a use claim without setting forth the steps involved in the process is an improper definition of a process, under 35 U.S.C. See *Ex parte Dunki*, 153 USPQ 678 (Bd. App, 1967) and *Clin. Products v. Brenner,* 149 USPQ 475 (D.D.C., 1966). By deleting the claims the rejection would be overcome.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-27, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims lack adequate support in the specification. The term “prodrug” is not defined in the specification so as to ascertain the structures of the compounds that are included and/or

excluded by the term. In patent examination, it is essential for claims to be precise, clear, correct, and unambiguous. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). By deleting the term the rejection would be overcome.

Claims 19-20, 24, are drawn to mechanism by which the compounds work in the body. This is not a practical utility under the US patent practice. To ascertain the practical utility, one must read the specification into the claims contrary to several precedent decisions by US courts and Official practice. Even then, the claims would become duplicates of 21-23, 25. Under the US patent practice duplicates or substantial duplicates claims cannot be in the same application. The claims are attempts by applicant to claim treatment of all diseases known today and that may be discovered in the future, arising from the mechanism. They are reach-through claims and are no longer patentable under the US patent practice. A claim must stand alone to define the invention, and incorporation into the claims by reference to the specification or an external source is not permitted. *Ex parte Fressola,* 27 USPQ 2d 1608, BdPatApp & Inter. (1993). Applicant must show possession of the invention by describing it with all the claimed limitations. *Lookwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997). By deleting the claims the rejection would be overcome.

Claims 19-27, are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating all the diseases listed in claim 22 and the mechanisms thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

"'In the context of determining whether sufficient "utility as a drug, medicant, and the like in human therapy" has been alleged, It is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the [compounds and the utilities]

as obviously correct." *In re Jolles*, 628 F.2d 1327, 1332 (Fed. Cir. 1980), citing *In re Novak*, 306 F.2d 924 (CCPA 1962); see 340 F.2d 974, 977-78 (CCPA 1965).

"A specification disclosure which contains a teaching of the manner and process of making and using the invention . . . must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), Id. at 1566, quoting *Marzocchi*, 439 F.2d 220, 223 (CCPA 1971); *Fiers v. Revel,* 984 F.2d 1164, 1171-72 (Fed. Cir. 1993), quoting *Marzocchi*, 439 F.2d at 223; see also *Armbruster*, 512 F.2d 676, 677 (CCPA 1975); *Knowlton*, 500 F.2d 566, 571 (CCPA 1974); *Bowen*, 492 F.2d 859 (CCPA 1974); *Hawkins*, 486 F.2d 569, 576 (CCPA 1973).

Where there is "no indication that one skilled in the art would accept without question [the instant compounds and method of use] and no evidence has been presented to demonstrate that the claimed products do have those effects *Novak*, 306 F.2d at 928, an applicant has failed to sufficiently demonstrate sufficient utility and therefore cannot establish enablement.'" *In re Rasmusson,* 75 USPQ2d 1297 (CAFC 2005). The claimed invention is not enabled without undue experimentation for the following reasons:

For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered. *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988): "The factors to be considered [in making an enablement rejection] have been summarized as a) the breadth of the claims, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and, the quantity of experimentation necessary, *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex prate Formal*, 230 USPQ 546. The breath of the claims includes many compounds and

prodrugs thereof. The compounds embraced by the claims are so numerous and are in the hundreds of thousands or millions. The nature of the invention is using the compounds as pharmaceuticals. The specification fails to disclose any nexus between the instant compounds, their and treating the diseases in the claims. Applicant is also claiming the mechanism by which the compounds work in the body.

It is quite possible that a mutation in the gene for the protein responsible for kinase and/or a Src production may lead to increase levels. To use the invention as claimed, one of ordinary skill in the art would have to perform experimentation in every instance to determine if the increase is due to genetic mutation in a patient or not. After prospective patients are identified and treated, assays must be performed on each one to determine if treatment is successful. Such is deemed undue experiment under the US patent practice. Even then, the specification fails to disclose a routine procedure to perform such assays. Therefore, to make and use the instant invention, one of ordinary skill in the art would have to perform significant amount of experimentation.

For a compound to prevent and/or treat all forms of cancers (tumors) it must be effective against all the five categories of cancers, namely: carcinoma, sarcoma myeloma, leukemia, lymphoma and mixed types. There is no evidence in the instant specification that the claimed compound satisfied this requirement. There is no evidence that the instant compounds would treat or prevent all forms of cancers before the occurrence of cancers. According to Matthews et al., Cancer Res. (2007), Vol. 67(6), pages 2430-2438 (www.aacrjournals.org), not only is cancer in human requires chronic exposure to a combination of tumor promoters, activating protein and nuclear factor activation are required during promotion and progression of cancers. For example, cervical cancer may be initiated by exposure to HPV (e.g. HPV16) it requires many years of promotion such as exposure to estrogen as well as exposure to HPV16-E7 oncoprotein. See

Matthews et al., *Ibid.* However, the authors state that skin carcinogenesis is unique for not requiring nuclear activation.

The specification fails to disclose routine procedure how "normal" people would be identified and treated before the occurrence of each form of cancers.

The "fact that [the] art of cancer chemotherapy is highly unpredictable places on drug patent applicants to provide basis for believing speculative statements placed in the specification as positive assertion are true, and failing such, ignorance of PTO in not being able to provide scientific reason why assertion is not sound is not justification for permitting assertion to be made, where those of ordinary skill in the art would not accept assertions as believable without some data or other evidence to support it." *In re Hozumi,* 226 USPQ 353, (ComrPats, 1985). "Proof of utility is sufficient if it is convincing to one [of] ordinary skill in the art, amount of evidence required depends on facts of each individual case, character and amount of evidence needed may vary, depending on whether alleged utility appears to accord with or to contravene scientific principles and beliefs." *In re Jolles,* 206 USPQ 885 (CCPA, 1980).

Even though "the state of cancer treatment has advanced remarkably, decisional law would seem to indicate that the [instantly claimed] utility is sufficiently unusual to justify an examiner's requiring substantial evidence, which may be in the form of animal tests." *Ex parte Krepelka, et al.,* 231 USPQ 746 (BdPatApp&Int, 1986).

The statements on pages 1-4, are speculations since there is no conclusive evidence in support thereof. There is no evidence in the specification that established correlation between the disclosure and the instantly claimed invention. *See Ex parte Mass*, 9 USPQ2d 1746, (1987).

MPEP 2164.01(a) states, "[a] conclusion of lack of enablement means that, based on the evidence regarding any of the above factors, the specification, at the time the application was

filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 19-27, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For the reasons set forth above under 35 USC 112, first paragraph the claims are indefinite. See the Examiner's suggestions above.

Claims 19-23, are duplicates of 18. Under the US patent practice intended use cited in the claims is not a limitation in a compound or composition claim. *In re Hack*, 114USPQ 161 (CCPA, 1957); In *re Craig*, 90 USPQ 33 (CCPA, 1951); *In re Brenner*, 82 USPQ 49 (CCPA, 1949). Also under the US patent practice duplicate or substantial duplicate claims cannot be in the same application. By deleting the claims the rejection would be overcome.

The term "prodrug" is not claimed or defined in claim 6. Therefore, it is not possible to determine the metes and bounds of claims 19-27. The claims are indefinite.

Objection

Claims 6-7, 16, 18, are objected because, according to the claims, R3-R6 do not form rings in formula (I). Therefore, formula (I) must be amended accordingly.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, Art Unit 1625

May 13, 2010